

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

LIFE TECHNOLOGIES CORPORATION,
and APPLIED BIOSYSTEMS, LLC,,

Plaintiffs

V.

BIOSEARCH TECHNOLOGIES, INC.,
BIO-SYNTHESIS, INC., and EUROFINS
MWG OPERON INC.,

Defendants.

CIVIL ACTION NO. 2:09-cv-00283

**DEFENDANTS BIOSEARCH TECHNOLOGIES, INC. AND EUROFINS MWG
OPERON INC.'S MOTION TO RECONSIDER THE MAGISTRATE'S CLAIM
CONSTRUCTION ORDER**

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I. INTRODUCTION

On September 22, 2011, Magistrate Everingham issued his Memorandum Opinion and Order (Dkt. No. 212) (“Order”) on the construction of claims of the patents asserted by Plaintiffs Life Technologies Corporation (“LifeTech”) and Applied Biosystems, LLC (“ABI”) (collectively, “Plaintiffs”) in this action, including: U.S. Patent Nos. 5,538,848 (the “’848 patent”); 5,723,591 (the “’591 patent”); 5,876,930 (the “’930 patent”); 6,030,787 (the “’767 patent”); and 6,258,569 (the “’569 patent”) (collectively, the “Patents-In-Suit”). Defendants Biosearch Technologies, Inc. (“Biosearch”) and Eurofins MWG Operon Inc. (“Eurofins”) (collectively, “Defendants”) respectfully object to the Order.

Defendants’ claim construction brief stressed that claim construction interpretation requires considering all the evidence at issue, both intrinsic evidence and, when appropriate, extrinsic evidence. The Court made several errors by improperly applying the law and by ignoring certain facts. Defendants request that the Court reconsider the construction of the terms according to Defendants’ arguments presented below.

II. TERMS AT ISSUE

A. Defendants Object to the Court’s Interpretation of “Quencher” Because Claim Interpretation Requires Consideration of All of the Intrinsic Evidence.

The Court erred when interpreting “quencher” because it failed to properly interpret the claim under well known canons of construction that includes an analysis of the specification, the other claims of the patent, and the file history of the patent and its related members. Rather than consider all the intrinsic evidence, the Court essentially focused solely on the specification.

As stated in *Phillips*, “[b]ecause claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005).

Furthermore, the Federal Circuit has repeatedly held that the prosecution file history is always relevant to a proper interpretation of a claim term. For example, “[w]e cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.” *Phillips*, 415 F.3d at 1313 (quoting *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005)). The prosecution history should serve to illuminate: (1) the presence of possible infringement; (2) whether prosecution history estoppel places any limitations on what infringes a claim; and (3) proper claim construction. *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1559-60 (Fed. Cir. 1996); *see also SSIH Equip. S.A. v. U.S. Int’l Trade Comm’n*, 718 F.2d 365, 376 (Fed. Cir. 1983) (“Prosecution history is always relevant to a proper interpretation of a claim.”).

The Court repeatedly emphasized the fact that Plaintiffs’ construction was found verbatim in the specification. However, as outlined in *Phillips*, *Amhil Enters.*, and *SSIH Equip. S.A.*, a proper claim construction analysis cannot, and does not, end with the specification. Rather, the Court should have considered the other claims of the patent and the file history in its claim construction analysis.

1. The Same Term Cannot Be Construed Differently for Different Claims

The Court stated that:

Although the claims of the Livak patent [sic, patents] **require**, in some instances, that the quencher molecule emit light so that a certain ratio might be determined, the court will not read such a limitation in all of the claims of the Livak patents.

Order at 11 (emphasis added).

The same claim term in two different claims should not have different meanings. The Federal Circuit has repeatedly upheld the principle that “if a claim term appears in more than one claim it should be construed the same in each.” *Dayco Prods. Inc. v. Total Containment, Inc.*,

329 F.3d 1358, 1371 (Fed. Cir. 2003).

The Court has agreed that some of the claims **require** the term “quencher” be interpreted as a “fluorescent quencher”; as such, this interpretation must be applied to all the claims that recite “quencher.”

2. **A Claim Term Cannot Be Construed to Render “Nonsensical” Results for Some of the Claims**

The law that a claim term must be interpreted the same in all the claims goes hand in hand with the law that states a claim interpretation that renders the claim “nonsensical” cannot be correct. The Federal Circuit has spoken numerous times to this point, namely, that a claim cannot be interpreted in a way that makes another claim using that term in the same patent nonsensical. *See Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1357 (Fed. Cir. 2006) (holding that Plaintiff’s proposed construction in claim 1 cannot be correct because it renders claim 2 nonsensical, despite the specification specifically allowing for Plaintiff’s construction). “A claim construction that renders asserted claims facially nonsensical ‘**cannot** be correct.’” *Becton, Dickinson & Co. v. Tyco Healthcare Group LP*, 616 F.3d 1249, 1255 (Fed. Cir. 2010) (quoting *Schoenhaus*, 440 F.3d at 1357) (emphasis added). In *Board of Regents of the University of Texas System v. BenQ America Corp.*, 533 F.3d 1362, 1370 (Fed. Cir. 2008), the Federal Circuit similarly stated “[w]e decline to adopt a construction that would effect this nonsensical result.” Furthermore, a very recent Federal Circuit decision reiterates this principle. In *ALA Engineering Ltd. v. Magotteaux Int’l S/A*, No. 2011-1058, 2011 U.S. App. LEXIS 18125, at *26-27 (Fed. Cir. August 31, 2011), the Federal Circuit again declined to give a claim term an interpretation that would render the claims “absurd” and “nonsensical.” *Id.* at *27 (citing *Bd. of Regents of the Univ. of Tex. Sys.*, 533 F.3d 1362, 1370 (Fed. Cir. 2008)).

As shown above, the Court stated that:

Although the claims of the Livak patent [sic, patents] **require**, in some instances, that the quencher molecule emit light so that a certain ratio might be determined, the court will not read such a limitation in all of the claims of the Livak patents.

Order at 11 (emphasis added).

If a claim limitation is “required” in some claims, it is required in all. The Federal Circuit does not allow an interpretation that would render claims nonsensical, and thus, the Court’s interpretation “cannot be correct”. *Becton Dickinson*, 616 F.3d at 1255.

3. Plaintiffs Clearly Disavowed Non-fluorescent Quenchers during Prosecution

The Court also states that the file history does not show a “clear disclaimer of claim scope.” Order at 11. The doctrine of prosecution disclaimer dictates that a claim can be limited by file history statements if the patentee takes a position before the PTO that would lead a competitor to believe that the applicant had disclaimed coverage of the subject matter. *See Inverness Med. Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380 (Fed. Cir. 2002) (“[t]o be sure, failure to object to an examiner’s interpretation of a claim ordinarily disclaims a broader interpretation.”); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 736 (2002) (“[A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.”).

In the ‘930 file history, claim 17 included a limitation that the ratio of fluorescence intensities of the reporter and the quencher was calculated. The Examiner rejected the claim as indefinite:

Claim 17 is indefinite in the recitation of the “ratio of fluorescent intensities of said reporter molecule to said quencher molecule” in that the quencher molecule in this claim was not recited as being fluorescent so it is unclear what “intensities” are actually being compared to arrive at a ratio. See office action dated 1/21/1997 page 4.

‘930 Prosecution History, January 21, 1997 Office Action at 4 ¶ c (Ex. A to Defendants’ Claim Construction Brief) (Dkt. No. 192-1).

In response, the patentee amended the claim to recite “fluorescent quencher.” This is a direct disavowal of non-fluorescent quenchers in claims that recite ratios of reporters and quenchers, and, as required by the Federal Circuit, it is a “clear and unmistakable” disavowal. *See Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003); *see also Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995) (“Arguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary.”).

Significantly, the Court overlooked the fact that this doctrine applies even to the earlier issued ‘848 and ‘591 patents. *See Ormco Corp. v. Align Tech. Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007) (“When the application of prosecution disclaimer involves statements from prosecution of a familiar patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familiar application are relevant in construing the claims at issue.”).

Thus, the totality of the intrinsic evidence, including the prosecution history’s clear disavowal of non-fluorescent quenchers in certain claims and a uniform interpretation of claim terms to avoid “absurdity,” shows that the Court’s interpretation was incorrect.

B. Defendants Object to the “Hairpin” Construction Because the Inventor Modified the Definition, Using the Term Differently in the File History.

As shown above, proper claim construction requires consideration of the specification, other claims, and the file history. As a preliminary matter, the Court misread the cited specification quotation and apparently did not consider the entire quotation from the specification.

Probes containing a reporter molecule - quencher molecule pair have been developed for hybridization assays **where the probe forms a hairpin structure**, i.e., where the probe hybridizes to itself to form a loop such that the quencher molecule is brought into proximity with the reporter molecule in the absence of a complementary nucleic acid sequence to prevent the formation of the hairpin structure. **WO 90/03446**; European Patent Application No. 0 601 889 A2. When a complementary target sequence is present, hybridization of the probe to the complementary target sequence **disrupts the hairpin structure** and causes the probe to adopt a conformation where the quencher molecule is no longer close enough to the reporter molecule to quench the reporter molecule. As a result, the probes provide an increased fluorescent signal when hybridized to a target sequence than when unhybridized. **Probes including a hairpin structure** have the disadvantage that they can be difficult to design and may interfere with the hybridization of the probe to the target sequence.

'591 patent at 1:46-63 (Ex. B to Plaintiffs' Claim Construction Brief) (Dkt. No.181-1) (emphasis added).

The excerpt above clarifies that it is the **probe** that contains a) a hairpin structure and b) reporters and quenchers that are brought into proximity when the hairpin structure is present. A "hairpin structure" does not, by itself, require the reporter and quencher molecules, as the Court ruled.

In fact, the specification references the WO90/03446 application, which contains **fourteen** figures including hairpin structures, none of which includes a single reporter or quencher molecule. WO 90/03446 (Ex. B to Defendants' Claim Construction Brief) (Dkt. No. 192-2). Plaintiffs specifically cited structures that do not contain reporter and quencher molecules as support for the definition of "hairpin structure," however, this does not support the Court's construction.

Furthermore, the Court failed to consider the file history statements, which is clear error under *Phillips*. As discussed above, the doctrine of prosecution disclaimer dictates that a claim can be limited by file history statements if the patentee takes a position before the PTO that

would lead a competitor to believe that the applicant had disclaimed coverage of the subject matter. *See Inverness*, 309 F.3d at 1380; *see also Phillips*, 415 F.3d at 1317 (quoting *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580 (Fed. Cir. 1988) (“The purpose of consulting the prosecution history in construing a claim is to ‘exclude any interpretation that was disclaimed during prosecution.’”).

In the file history of the ‘591 patent, the patentee stated:

The Specification thus clearly defines what is intended by the term “hairpin structure”. This definition for the term “hairpin structure” is consistent with other art references which employ the term “hairpin structure”. See U.S. Patent No. 5,607,834 [Exhibit 1] (“a hairpin consists of a base paired double-helical region, the stem, with a loop of unpaired bases at one end.”)

‘591 Prosecution History, Aug. 6, 1997 Response (Ex. G to Plaintiffs’ Claim Construction Brief at 2-3) (Dkt. No. 181-6). Thus, Plaintiffs themselves define a “hairpin structure” as a structure that does not require the presence of reporter and quencher molecules that can be brought into proximity.

The Court failed to properly consider all of the intrinsic evidence, including additional statements in the specification and file history. This supports a finding that a “hairpin structure” does not require the presence of reporter and quencher molecules.

C. One of Skill in the Art Would Not Have Interpreted “Monitoring” to Include “Real Time Monitoring.”

1. The Court Mischaracterizes the Higuchi Art as “Simple”

The Court pointed to Russell Higuchi’s 1993 article (“Higuchi”) as disclosing “a simple, quantitative assay, for any amplifiable DNA sequence that uses a video camera to monitor multiple polymerase chain reactions (PCRs) simultaneously over the course of thermocycling.” Order at 17. While the author may have self-characterized his technology as such, a fair reading of the article reiterates that this technology is not “simple.” In fact, several other statements in

the article indicate the opposite: the technology is much more complicated than the Court suggests.

As a preliminary matter, Higuchi's technology relates to a different method of obtaining fluorescence, relying on unlabeled probes¹. As shown below, whether Higuchi's technology could or would apply to monitoring reactions using the dual-labeled probes of the Patents-In-Suit has not been established.

Higuchi included a block diagram in his article that illustrates the complexity of the monitoring technology.

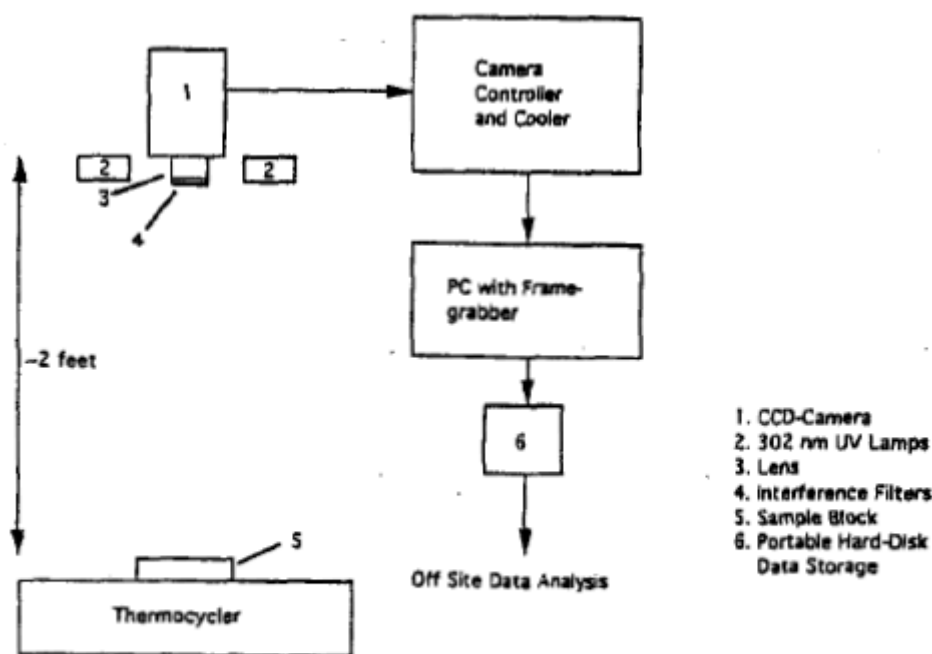


FIGURE 1. Block diagram of video camera system used to monitor amplifications in thermocycler. See Experimental Protocol for more details.

Higuchi at 1026, Fig. 1 (Ex. Y to Plaintiffs' Reply Brief) (Dkt. No. 201-2).

This instrumentation is described as follows:

¹ Higuchi relies on "intercalating dyes", which are not attached to a probe, nor is a probe used in the Higuchi reactions. Rather, the dye will bind preferentially to double stranded nucleic acid.

The video camera used is a STAR 1 system from Photometrics (Tuscon [sic], Arizona). It uses a thermoelectrically cooled 384 x 560 CCD array with a 12 bit A/D controller. Exposure times can be varied to change sensitivity to the fluorescence being detected. Typically exposures of 1 sec. were used with virtually no thermal or random noise. Illumination is provided by two Chroma-Vue, 302 nm, mid-range U.V. lamps from U.V. products (San Gabriel, CA). A PC Vision Plus frame grabber board (Imaging Technology, Inc., Woburn, Mass.) and Jandel Scientific's (San Raphael, CA) JAVA image analysis software was used to quantitate areas of interest in the captured image. Bernoulli 90 MB removable disks from IOMEGA Corp. were used for image storage and as a means of providing unlimited storage. Data analysis was done using Microsoft Excel 4.0.

Id. at 1026. To classify this system as "simple" is incorrect.

Furthermore, the article describes a number of complications and uncertainties related to this technology by referring to the variance in fluorescence values:

There is a considerable variance in the initial fluorescence values obtained from the different amplifications even though it is expected that these initial values should be the same (the varying amounts of single-stranded template DNA are so small that they have a negligible effect on the total fluorescence). The sources of this variation are apparently inhomogeneity of illumination, parallax, and variable attenuation of the fluorescence due to the tube caps. We have found that viewing amplifications without caps but through a vapor barrier of mineral oil or Ampliwax reduces, but does not eliminate, this variation.

Id. at 1027.

Finally, the article ends by recognizing that more experimentation remains to be done:

We are working to improve kinetic PCR analysis through improvements in instrumentation, signal generation and by increasing the specificity and reproducibility of PCR. For example, we are automating the collection of the sample images and their quantitation. And although the normalization procedure we have described here can compensate, we wish to further minimize sample-to-sample fluorescence variation. This may involve the use of alternative illumination and/or detection formats as well changes in the composition and/or structure of the amplification vessel. **We are also testing alternative dyes and intercalators and alternative strategies of detection using**

optically active probes based on the 5'-3' exonuclease activity of Taq DNA polymerase. We are working on procedures that may help increase the specificity of a PCR, including a one-tube, nested-primer approach (Higuchi and Erlich, manuscript in prep.). Lastly, we are trying to reduce the “primer-dimer” artifact, which may improve reproducibility of the reaction profile at extremely low levels of target DNA.

Id. at 1030 (emphasis added).

Through the emphasized language, Higuchi was “testing” whether “optically active probes” such as the dual-labeled probes of Livak would work in the assay. One of skill in the art would certainly not read this statement to suggest that dual labeled probes could be monitored in real time using Higuchi’s technology; rather, one of skill in the art would understand the technology was not yet developed.

Higuchi understood, and communicated the fact, that the PCR monitoring technology discussed in his article was quite complicated; or at least certainly not as simple as the Court implies. Higuchi himself suggests that additional work would need to be done to determine the applicability of his technology to dual-labeled probes.

Finally, if the technology to monitor reactions in real time was so “simple,” the Plaintiffs would have utilized it. Plaintiffs certainly knew of the technology and emphasized repeatedly the benefit of monitoring in real time as shown in the specification, yet did not utilize the theoretically “simple” process.

2. The Court Incorrectly Interpreted RT-PCR as “Real Time” Rather Than “Reverse Transcriptase”

The Court states that Dr. Livak’s 1996 article explains that “[r]esearchers have developed several methods of quantitative PCR and RT-PCR and describes different methods that measure product during PCR reactions.” Order at 17 (citing Heid et al., *Genome Research*, 6:989-994 (1986) at 986 (Ex. C to Defendant’s Claim Construction Brief) (Dkt. No. 192-3)). In doing so,

the Court concludes that Dr. Livak's article does not support an interpretation limited to end point monitoring.

Unfortunately, the Court has misunderstood the difference between "reverse transcriptase PCR," rather confusingly termed "RT-PCR" in Dr. Livak's article, and "real time PCR." Heid et al., *Genome Research*, 6:989-994 (1986) at 986 (Ex. C to Defendant's Claim Construction Brief) (Dkt. No. 192-3)) ("Recently, PCR has proven to be a powerful tool for quantitative nucleic acid analysts. PCR and reverse transcriptase (RT)-PCR have permitted the analysis of minimal starting quantities of nucleic acid. . . ."). Thus, the Court's statement that the article describes "different methods that measure product during PCR reactions" is incorrect; the article describes different methods of **reverse transcriptase PCR**.

Thus, the teachings of the Livak article fully support an interpretation that Dr. Livak himself believes he invented a "novel" real time method after access to the ABI Prism machine, two years after the filing date.

3. A Person Having Ordinary Skill in the Art Would Not Interpret "Monitoring" in Livak to Include "Real-Time Monitoring" at the Time of Patent Application

Claim terms are interpreted as having "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313. When a claim term understood to have a narrow meaning when the application is filed later acquires a broader definition, the literal scope of the term is limited to what it was understood to mean at the time of filing." *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1363 (Fed. Cir. 2005) (quoting *Kopykake Enters., Inc. v. Lucks Co.*, 264 F.3d 1377, 1383 (Fed. Cir. 2001)). Plaintiffs improperly attempt to capture later-developed technology that was not understood to be encompassed by "monitoring the fluorescence" at the time of the invention.

The Court mischaracterizes the correct legal standard:

The court, therefore, rejects Defendants' contention that the inventors did not intend to include methods of real-time monitoring in the Livak patents.

Order at 18. The standard is not the "inventor's intention"; rather, the standard is what one of skill in the art would interpret the claim to mean at the time of the invention.

When the patent application was filed on November 16, 1994, the simple fact was that a person having ordinary skill in the art would not understand "monitoring fluorescence" to include monitoring fluorescence in real-time. From 1992, the date of Higuchi's first article regarding "real time monitoring," to 1996, the date that Plaintiffs launched the real time ABI Prism machine, Defendants have been unable to find a single additional reference other than the Higuchi references that utilize real time monitoring. Thus, one of skill in the art would clearly not have interpreted "monitoring the fluorescence" to include real time monitoring.

III. CONCLUSION

For the above reasons, Defendants respectfully move to reconsider the Order.

Dated: October 6, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing document has been served on all counsel of record via the Court's Case Management/Electronic Case Filing and/or electronic mail on October 6, 2011.

/s/ Daniel Johnson, Jr.

Daniel Johnson, Jr.

CERTIFICATE OF CONFERENCE

This motion is opposed. Pursuant to Local Rule CV-7(h), counsel for Biosearch and Eurofins contacted Plaintiffs' counsel requesting their consent to reconsider the Court's claim construction Opinion and Order. Counsel stated that Plaintiffs oppose the motion for reconsideration.

/s/ Daniel Johnson, Jr.

Daniel Johnson, Jr.